Complete Summary

GUIDELINE TITLE

Prevention of varicella: updated recommendations of the Advisory Committee on Immunization Practices (ACIP).

BIBLIOGRAPHIC SOURCE(S)

Prevention of varicella. Updated recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 1999 May 28;48(RR-6):1-5. [10 references] PubMed

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SCOPE

DISEASE/CONDITION(S)

Varicella zoster viral infections: varicella (chickenpox) and herpes zoster (shingles).

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Family Practice Internal Medicine Obstetrics and Gynecology Pediatrics

INTENDED USERS

Advanced Practice Nurses Physician Assistants Physicians Public Health Departments

GUI DELI NE OBJECTI VE(S)

- To advise physicians on the use of live, attenuated varicella virus vaccine and the use of varicella zoster immune globulin (VZIG) as prophylaxis against varicella.
- To update previous recommendations on the prevention of varicella.

TARGET POPULATION

Children 12 months old or older; Adolescents; Adults

INTERVENTIONS AND PRACTICES CONSIDERED

Vaccination with live, attenuated varicella virus (VARIVAX, Merck and Company, Inc.); varicella zoster immune globulin (VZIG) and acyclovir prophylaxis.

MAJOR OUTCOMES CONSIDERED

- Incidence of infection by varicella zoster virus, which can lead to varicella (chickenpox), and herpes zoster (shingles)
- Efficacy of vaccination
- Adverse events associated with vaccination

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

VARICELLA VACCINATION

Note: The National Guideline Clearinghouse (NGC) has incorporated the updated guidelines on prevention of varicella issued in 1999 into the following summary of the major recommendations issued by the Advisory Committee on Immunization Practices (ACIP) in 1996. The updated guidelines address:

- Establishing child care and school entry requirements
- Use of the vaccine following exposure and for outbreak control
- Use of the vaccine for some children infected with the human immunodeficiency virus (HIV)
- Vaccination of adults and adolescents at high risk for exposure

Day Care and School Entry Requirements:

Because varicella incidence is highest among children aged 1-6 years, implementing vaccination requirements for child care and school entry will have the greatest impact on reducing disease incidence. ACIP recommends that all states require that children entering child care facilities and elementary schools either have received varicella vaccine or have other evidence of immunity to varicella. Other evidence of immunity should consist of a physician's diagnosis of varicella, a reliable history of the disease, or serologic evidence of immunity. To prevent susceptible older children from entering adulthood without immunity to varicella, states should also consider implementing a policy that requires evidence of varicella vaccination or other evidence of immunity for children entering middle school (or junior high school).

Persons less than 13 years of age:

- Persons less than 13 years of age should receive one 0.5-ml dose of vaccine subcutaneously.
- Children who have not been vaccinated previously and who lack a reliable history of varicella infection are considered susceptible.

12-18 months of age:

All children should be routinely vaccinated at 12-18 months of age. Varicella virus vaccine may be administered to all children at this age regardless of prior history of varicella; however, vaccination is not necessary for children who have reliable histories of varicella.

19 months-12 years of age:

- Varicella vaccine is recommended for all susceptible children by the 13th birthday.
- Varicella virus vaccine should be administered to susceptible children during the routine immunization visit at 11-12 years of age but may be administered at any time during childhood.

Persons greater than or equal to 13 years of age:

- Persons in this age group should be administered two 0.5-ml doses of vaccine, subcutaneously, 4-8 weeks apart.
- Vaccination is recommended for susceptible persons who have close contact with persons at high risk for complications (e.g., health-care workers and family contacts of immunocompromised persons).
- Vaccination should be considered for susceptible persons in the following groups who are at high risk for exposure:
 - 1. Persons who live or work in environments in which transmission of varicella zoster virus (VZV) is likely (e.g., teachers of young children, day-care employees, and residents and staff in institutional settings).
 - 2. Persons who live or work in environments in which varicella transmission can occur (e.g., college students, inmates and staff of correctional institutions, and military personnel).
 - 3. Nonpregnant women of childbearing age. Women should be asked if they are pregnant and advised to avoid pregnancy for 1 month following each dose of vaccine.
 - 4. Adolescents and adults living in households with children

- 5. International travelers who do not have evidence of immunity to VZV (e.g., serologic tests).
- Vaccination of other susceptible adolescents and adults is desirable and may be offered during routine health-care visits.

Vaccination of HIV-Infected Children and Other Persons With Altered Immunity:

ACIP has previously recommended that varicella vaccine should not be administered to persons with primary or acquired immunodeficiency, including immunosuppression associated with acquired immunodeficiency syndrome (AIDS) or other clinical manifestations of human immunodeficiency virus (HIV) infections, cellular immunodeficiencies, hypogammaglobulinemia, and dysgammaglobulinemia. ACIP maintains its recommendation that varicella vaccine should not be administered to persons who have cellular immunodeficiencies, but persons with impaired humoral immunity may now be vaccinated. In addition, some HIV-infected children may now be considered for vaccination. Because children infected with HIV are at increased risk for morbidity from varicella and herpes zoster (i.e., shingles) compared with healthy children, ACIP recommends that, after weighing potential risks and benefits, varicella vaccine should be considered for asymptomatic or mildly symptomatic HIV-infected children in CDC class N1 or A1 with age-specific CD4+ T-lymphocyte percentages of greater than or equal to 25%. Eligible children should receive two doses of varicella vaccine with a 3-month interval between doses. Because persons with impaired cellular immunity are potentially at greater risk for complications after vaccination with a live vaccine, these vaccinees should be encouraged to return for evaluation if they experience a postvaccination varicella-like rash. The use of varicella vaccine in other HIV-infected children is being investigated further. Recommendations regarding use of varicella vaccine in persons with other conditions associated with altered immunity (e.g., immunosuppressive therapy) have not changed.

Postexposure Vaccination and Outbreak Control:

ACIP now recommends the vaccine for use in susceptible persons following exposure to varicella. If exposure to varicella does not cause infection, postexposure vaccination should induce protection against subsequent exposure. If the exposure results in infection, no evidence indicates that administration of varicella vaccine during the presymptomatic or prodromal stage of illness increases the risk for vaccine-associated adverse events. Although postexposure use of varicella vaccine has potential applications in hospital settings, vaccination is routinely recommended for all susceptible health-care workers and is the preferred method for preventing varicella in health-care settings.

Varicella outbreaks in some settings (e.g., child care facilities, schools, institutions) can last 3-6 months. Varicella vaccine has been used successfully by state and local health departments and by the military for outbreak prevention and control. Therefore, state and local health departments should consider using the vaccine for outbreak control either by advising exposed susceptible persons to contact their health-care providers for vaccination or by offering vaccination through the health department. Guidelines for varicella outbreak investigation and control are available from the National Immunization Program (NIP), CDC.

USE OF VARICELLA ZOSTER IMMUNE GLOBULIN (VZIG) FOR POSTEXPOSURE PROPHYLAXIS: (Summarized by NGC)

- VZIG provides maximum benefit when administered as soon as possible after the presumed exposure, but it may be effective if administered as late as 96 hours after exposure.
- The recommended dose of VZIG is 125U/10 kg (22 lbs) body weight, up to a maximum of 625 U. The minimum dose is 125 U; fractional doses are not recommended.
- VZIG should be administered intramuscularly as directed by the manufacturer. VZIG should never be administered intravenously.
- The decision to administer VZIG to a person exposed to varicella should be based on a) Whether the patient is susceptible, b) whether the exposure is likely to result in infection, and c) whether the patient is at greater risk for complications than the general population.

Recommendations for the Use of VZIG:

Persons less than 13 years of age:

Immunocompromised children. VZIG primarily is used for passive immunization of susceptible, immunocompromised children after substantial exposure to varicella or herpes zoster - including children who a) have primary and acquired immunedeficiency disorders b)have neoplastic diseases and c) are receiving immunosuppressive treatment.

To insure protection against severe disease, immunocompromised persons receiving intravenous immunoglobulin should be administered VZIG if exposed to wild-type VZV.

VZIG is indicated for neonates whose mothers have signs and symptoms of varicella within 5 days before and 2 days after delivery.

Premature infants who are less than 28 weeks gestation or who weigh less than or equal to 1000g at birth who are exposed to VSV should receive VZIG, regardless of maternal history, because such infants may not have acquired maternal antibody. Most premature infants of greater than or equal to 28 weeks' gestation born to immune mothers have enough acquired maternal antibody to protect them from severe disease and complications.

Persons greater than or equal to 13 years of age:

To prevent complications, immunocompromised persons who are considered susceptible and who have had substantial exposure to varicella should receive VZIG.

The decision to administer VZIG to susceptible, healthy adolescents and adults should be made on an individual basis. When deciding whether to administer VZIG, clinicians should consider the patient's health status, the type of exposure, and the likelihood of previous varicella infection.

VZIG should be strongly considered for susceptible pregnant women who have been exposed. Neonates born to mothers who have signs and symptoms of varicella within 5 days preceding or 2 days after delivery should receive VZIG regardless of whether the mother received VZIG.

CLINICAL ALGORITHM(S)

None provided.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVI DENCE SUPPORTING THE RECOMMENDATIONS

Not stated

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Prevention of varicella infection and complications
- Modification of varicella severity

POTENTIAL HARMS

Varicella Vaccine

Based on data on potential adverse events associated with varicella vaccine, available from the Vaccine Adverse Event Reporting System (VAERS), it is likely that serious adverse events following vaccination occur at a substantially lower rate than following natural disease. Serious adverse events have included encephalitis, ataxia, erythema multiforme, Stevens-Johnson syndrome, pneumonia, thrombocytopenia, seizures, neuropathy, and herpes zoster. The VAERS rate of herpes zoster after varicella vaccination was 2.6/100,000 vaccine doses distributed.

Vaccine-associated adverse events include mild varicella-like rash at the injection site, nonlocalized varicella-like rash, and complaints around the injection site (i.e., pain/soreness, swelling, erythema, rash, pruritis, hematoma, induration, and stiffness); anaphylactic or allergic reactions to vaccine components. Rash is the most frequently reported adverse event (rate: 37/100,000 vaccine doses distributed).

Transmission of the vaccine virus is rare and has been documented in immunocompetent persons by polymerase chain reaction (PCR) analysis on only three occasions out of 15 million doses of varicella vaccine distributed. All three cases resulted in mild disease without complications.

Varicella Zoster Immune Globulin (VZIG)

The most frequent adverse reaction following VZIG administration is local discomfort at the injection site. Pain, redness and swelling occur at the injection site in approximately 1% of persons. Less frequent adverse events include gastrointestinal symptoms, malaise, headache, rash, and respiratory symptoms, which occur in approximately 0.2% of recipients. Severe events, such as angioneurotic edema and anaphylactic shock, are rare (i.e., occurring in approximately less than 0.1% of recipients).

Subgroups Most Likely to be Harmed:

Persons with impaired cellular immunity are potentially at greater risk for complications after vaccination with a live vaccine.

Varicella virus vaccine should not be administered to persons who have a history of anaphylactic reaction to neomycin or gelatin.

Vaccination of persons who have severe illness should be postponed until after recovery.

Varicella virus vaccine should not be administered to persons who have any malignant condition (except acute lymphoblastic leukemia in remission under a research protocol), primary or acquired cellular immunodeficiency, persons who have a family history of congenital or hereditary immunodeficiency in first degree relatives, or persons receiving immunosupressive therapy, except children who have acute lymphoblastic leukemia in remission, as previously described.

Varicella vaccine should not be administered to pregnant women or women who are likely to become pregnant within one month of vaccination.

QUALIFYING STATEMENTS

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Current data concerning vaccine efficacy and persistence of antibody in vaccinees are based on research that has been conducted when natural varicella zoster virus (VZV) infection has been highly prevalent and has not been affected by wide use of the vaccine. Thus, the extent to which the protection provided by vaccination has been increased by boosting from exposure to natural virus and whether longer term immunity may wane as the circulation of natural VZV decreases are unknown.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Prevention of varicella. Updated recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 1999 May 28;48(RR-6):1-5. [10 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 May

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

GUI DELI NE COMMITTEE

Advisory Committee on Immunization Practices (ACIP)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline presents updated recommendations for those issued in 1996 by the Centers for Disease Control and Prevention (<u>Prevention of varicella: recommendations of the Advisory Committee on Immunization Practices (ACIP)</u>. MMWR 1996; 45[No. RR-11]).

GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>Centers for Disease Control and Prevention Web site.</u>

Print copies: Available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on June 30, 1998. The information was verified by the guideline developer on December 1, 1998. The summary was

updated by ECRI on December 1, 1999. This updated information was verified by the guideline developer on May 1, 2000.

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